# Course Description

This course is designed to guide you in preparing a research proposal for submission to the Institutional Review Board. You will gain a deeper understanding of how to ensure the ethical treatment of human subjects and begin to write the first three chapters of your dissertation.

# University Learning Outcomes (ULO)

* **ULO1:**Knowledge of Human Cultures and the Physical and Natural World
* **ULO2:**Intellectual and Practical Skills
* **ULO3:**Personal and Social Responsibility
* **ULO4:**Integrative and Applied Learning­
* **ULO5:**Immersed in the Critical Concerns of the Sisters of Mercy of the Americas

# Program Learning Outcomes (PLO)

* **PLO1:** Articulate an educational organization's mission, goals, and guiding principles that distinguish the organization from others. (ULO1, 4)
* **PLO2:** Understand the foundational base of organizational theory and demonstrate the ability to bridge theory and practice. (ULO1, 2, 4)
* **PLO3:** Given scenarios of conflict, choose ethical courses of action consistent with Gospel values. (ULO3, 5)
* **PLO4:** Synthesize and analyze data to reveal relations and causality and convert raw data into actionable information. (ULO2, 4)
* **PLO5:** View problems and challenges through the lens of a scientist, seeking evidence-based conclusions. (ULO1, 2, 4)
* **PLO6:** Practice and model steward leadership in transforming organizations to better serve all constituents. (ULO3, 4, 5)
* **PLO7:** Demonstrate facility in the application of technology to solve problems, analyze and synthesize data, and manage information. (ULO1, 2, 4)

# Course Learning Outcomes (CLO)

* **CLO1:** Identify research problems while developing questions and hypotheses.
* **CLO2:** Perform a literature review and design a research plan that addresses a gap in the educational literature.
* **CLO3:** Design and outline a research methodology with a data analysis plan.
* **CLO4:** Assemble a research proposal for the Institutional Review Board (IRB).
* **CLO5:** Determine how to ensure the ethical treatment of human subjects in research.

# Student Expectations

Students are expected to do the following:

* Ask probing and insightful questions related to course content.
* Make meaningful and relevant connections and application to their own learning process.
* Be productive and contributing members of class discussions.

# Required Course Materials

Bolker, J. (1998). *Writing your dissertation in fifteen minutes a day: A guide to starting, revising, and finishing your doctoral thesis*. New York, NY: H. Holt. ISBN-10: 080504891X ISBN-13: 978-0805048919

Lovitts, B. E., & Wert, E. L. (2009). *Developing quality dissertations in the social sciences: A graduate student's guide to achieving excellence*. Sterling, VA.: Stylus. ISBN-10: 1579222617 ISBN-13: 978-1579222611

Rudestam, K. E., & Newton, R. R. (2014). *Surviving your dissertation: A comprehensive guide to content and process* (4th ed.). Newbury Park, CA: Sage. ISBN-10: 1452260974 ISBN-13: 978-1452260976

# Suggested Point Values

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Assessment** | **Point Value** | **Due** |
| **Week 1** | |  |  |
|  | Ch. 1 Submission | 45 |  |
|  | Ch. 2 Submission | 40 |  |
|  | Dissertation Committee Submission | 10 |  |
| **Week 2** | |  |  |
|  | Discussion: Research Guiding Questions | 25 |  |
|  | Discussion: Research Rationale | 25 |  |
|  | Improving Clarity Exercise | 15 |  |
|  | Research Design Exercise | 35 |  |
| **Week 3** | |  |  |
|  | Advisor Meeting Reflection | 20 |  |
|  | Sample and Data Sources | 20 |  |
|  | Data Collection | 20 |  |
|  | Reviewing a Bad Survey | 20 |  |
|  | Instruments and Procedures | 20 |  |
| **Week 4** | |  |  |
|  | Advisor Meeting Reflection | 25 |  |
|  | Discussion: Improving Data Analysis Plans | 25 |  |
|  | Data Analysis | 25 |  |
|  | Reflection: The Role of the Researcher | 25 |  |
| **Week 5** | |  |  |
|  | Discussion: The Belmont Report’s Guiding Principles | 25 |  |
|  | Discussion: Ethical Treatment | 25 |  |
|  | CITI Training and Certification | 200 |  |
| **Week 6** | |  |  |
|  | IRB001 | 100 |  |
|  | IRB004 | 10 |  |
|  | Improve the IRB Protocol Activity | 20 |  |
|  | Advisor Meeting Reflection | 25 |  |
| **Week 7** | |  |  |
|  | Discussion: Dissertation Obstacles | 25 |  |
|  | Reflection | 25 |  |
|  | The IRB Protocol Submission | 150 |  |
| **Total Points** | | **1000** |  |

# Course Schedule

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| --- | --- | --- |
| **Week** | **Start** | **End** |
| One | <insert start date> | <insert end date> |
| Two |  |  |
| Three |  |  |
| Four |  |  |
| Five |  |  |
| Six |  |  |
| Seven |  |  |

# Weekly Learning Modules

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| **Week One: Drafting Your Initial Dissertation Chapters** | | |
| ***Learning Objectives*** | ***Alignment*** | |
| * 1. Develop a draft of Ch. 1 based on feedback and research. | CLO1 | |
| * 1. Develop a draft of Ch. 2 based on feedback and research. | CLO2 | |
| ***Resources, Activities, and Preparation***  *Utilize these resources and complete these activities in preparation for your graded assignments.* | ***Alignment*** | ***AIE*** |
| **Readings**   * Ch. 1 & 2 of *Developing Quality Dissertations in the Social Sciences* * Ch. 4 of *Surviving Your Dissertation* * Guidelines for Format and Content of the Dissertation * [On the Value of Dissertation Writing Groups](https://chroniclevitae.com/news/2136-on-the-value-of-dissertation-writing-groups?cid=VTEVPMSED1) by Leonard Cassuto |  |  |
| **Tutorials**  During this course, you will be asked to use and participate in various technologies to complete activities and assignments.  **Review** the tutorials available on Blackboard, as needed.  **Click** the **Student Resources** button from the menu on the left. | N/A | N/A |
| **Weekly Participation and Discussion**  The purpose of the weekly discussions is to provide you with a way to synthesize the concepts presented in this course. Each week, you will respond to the discussion questions with a substantive post of 200 to 250 words that addresses all the prompts for the question by 11:59 p.m. EST of the listed due date. By the conclusion of each week, Sunday at 11:59 p.m. EST, you will make at least 1 substantive comment of 100 to 150 words to 3 of your classmates’ posts for each assigned discussion question. Your comments must further the discussion by following the RISE model for meaningful feedback. It is recommended that you check in periodically throughout the week to ensure that you are meeting the participation requirement.  **Review** the RISE Model for Peer Feedback, located on Blackboard. |  |  |
| ***Supplemental Resources and Activities***  *Explore these optional resources to deepen your understanding.* | ***Alignment*** | ***AIE*** |
| **CITI Training Information**  The Collaborative Institutional Training Initiative (CITI Program) is a leader in online training designed to educate faculty and students about issues involving human subject research. CITI’s training is accepted as the standard in research education for training at many institutions and organizations. Through the course, you will participate in several online modules and be tested on the information. When you complete the course, you will be given a certificate.  Because of length of time to complete, you may want to begin this training in Week 1. It will take approximately 20 hours to complete. |  |  |
| **Survey Research**  If you are planning to create your own survey, review the Learning Module for Week 3 because you will be submitting a draft of your survey, which will require testing and question development. You may wish to plan ahead. |  |  |
| **Weekly Meetings With Advisor**  Weekly Meetings need to be scheduled with your advisor. Plan accordingly. In Weeks 3, 4, & 6, you will submit a reflection about those meetings. |  |  |
| **Adobe Connect Live Discussion**  **Review** [Adobe Connect Resources](https://sites.gmercyu.edu/student-resources/adobe-connect-resources/).  **Participate** in the scheduled live session with the course instructor. This session will provide an overview of the course and discuss the major assignments in the course.  **Prepare** to ask questions concerning the content of the week and the course as a whole.  *Note:* A recorded lecture will be made available to those who are unable to attend the live session. |  | Live Discussion: lecture and discussion = **1 hour** |

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| ***Graded Assignments***  *Complete these graded assessments by the end of the week unless specified otherwise.* | | ***Alignment*** | ***AIE*** |
| **Ch. 1 Submission**  Ch. 1 of the dissertation is the introduction to the study. Use the revisions you’ve made since EDU 811 to submit a draft of your introduction.  **Submit** the draft of Ch. 1. | | 1.1 |  |
| **Ch. 2 Submission**  The literature review identifies what is known about the research topic. This chapter helps you develop your argument and shows the broader context for your work. Use the revisions you have made since completing EDU 811 to submit a draft of the literature review.  **Submit** the draft of Ch. 2. | | 1.2 |  |
| **Dissertation Committee Submission**  **Email** the drafts of Ch. 1 & 2, with revisions, to your two other dissertation committee members (readers) by Thursday.  **Request** that they review the components and provide you with edits, comments, and suggestions for improvement by Sunday.  *Note:* You may find that a reader will take a little while to respond. Proceed with whatever feedback you receive. What matters most is quality feedback.  **Submit** a completion note to Blackboard when you have emailed your readers. | | 1.1-1.4 |  |
| **Total** |  |  |  |

# Faculty Notes

**Course Setup**

**General Questions and Discussion Forum:** This course includes a discussion forum for general questions, comments, and concerns. This forum is intended for any course-related commentary not found within a specific weekly discussion. This forum is not graded. Make sure to monitor this forum for student posts. You are encouraged to make an announcement advertising this forum and monitor and post regularly to build engagement.

**Adobe Connect:** Consider posting an announcement asking students to submit any questions or topics they'd like addressed ahead of time. The instructor can then utilize those questions that come up in the first part of the week to tailor the live Adobe Connect class session that would be scheduled toward the later part of the week. That 1-hour synchronous session will allow students the opportunity to go over any questions they had with the homework and clarify any misconceptions they have about the course content. All Adobe Connect sessions should be recorded and a link to the recording be posted to the course page so any student who misses the session can review it later in the week.

*Note:* It is the instructor’s choice as to what day they will schedule the Adobe Connect Live Session, but it is recommended that they schedule this session for Wednesday of the week so students have plenty of time to review their homework prior to the deadline on Sunday.

**IRB Handbook:** Check that the IRB Handbook is the most recent version.

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| Week Two: Methodology | |  |  |
| ***Learning Objectives*** | | ***Alignment*** | |
| * 1. Develop your research context and methodology. | | CLO3 | |
| * 1. Explain your rationale for your research methodology. | | CLO3 | |
| * 1. Develop clear and concise research questions for dissertation research. | | CLO2 | |
| * 1. Evaluate research questions and improve clarity of research questions. | | CLO1-2 | |
| ***Resources, Activities, and Preparation***  *Utilize these resources and complete these activities in preparation for your graded assignments.* | | ***Alignment*** | ***AIE*** |
| **Complete** the [Qualitative and Quantitative Analysis Survey](http://media.gmercyu.edu/edu812/qualitative-quantitative-analysis-survey/story_html5.html?utm_medium=app_email&utm_source=lp_app&utm_source=task_activity). | |  |  |
| **Readings**   * Ch. 3 & 5 of *Surviving Your Dissertation*. * Ch. 4 *of Developing Quality Dissertations in the Social Sciences*. * Question Design for Investigations: Activities and strategies to help students. Government of South Australia PowerPoint. *SACE Board of SA*. Retrieved July 24, 2015. * Cresswell, J. Chapter 3 - Identifying a Research Problem * The [Web Center for Social Science Research](http://www.socialresearchmethods.net/kb/contents.php).   Review the [APA style blog](https://blog.apastyle.org/) for up-to-date tips on references, headings, and citations. | |  |  |
| **Advisor Meeting**  **Meet** with your advisor to discuss your methodology. | |  |  |
| **IRB and Dissertation Proposal**  You will begin working on the first four components of your IRB and Dissertation Proposal this week. When approved, these components will constitute the first half of your proposal.  Your dissertation advisor should review each of the components and respond to you by Sunday with edits, comments, and suggestions for improvement. | |  |  |
| ***Graded Assignments***  *Complete these graded assessments by the end of the week unless specified otherwise.* | | ***Alignment*** | ***AIE*** |
| **Discussion: Research Guiding Questions**  **Respond** to the following question by Thursday 11:59 p.m. (EST). Provide specific examples to support your answers:     * **Revise** your Research Guiding Questions, taking into account edits, comments, and suggestions from your dissertation advisor.   **Post** constructive criticism, clarification, additional questions, or your own relevant thoughts to 3 of your classmates' posts by 11:59 p.m. (EST) on Sunday. | | 1.1-1.4 |  |
| **Discussion: Research Rationale**  **Respond** to the following question by Thursday 11:59 p.m. (EST). Provide specific examples to support your answers:   * Review the PowerPoint slides of the lecture from University of Wisconsin on Research Design. * For your dissertation, explain the following:     + Will this study generate new knowledge?   + Will this study benefit students, educators, or community members?   + Will this study advance understanding or influence policy?   + Will this study fill gaps in existing knowledge or resolve current controversies?   + Will this study be exploratory, explanatory, or experimental?   **Post** the document in the Research Rationale discussion forum by Thursday.  **Post** constructive criticism, clarification, additional questions, or your own relevant thoughts to 3 of your classmates' posts by 11:59 p.m. (EST) on Sunday. | | 2.1-2.2 |  |
| **Improving Clarity Exercise**  To better ensure defined constructs, greater clarity, and research rigor, what should be improved in the following statements?   * The purpose of this study is to determine the major concerns of students after they enroll. * Which educational method of engaging students is better—technology or parental involvement? * Does the voluntary participation by faculty in orientation affect how they feel during the semester?   For each question, rewrite it to be more clear and concise. Define any variables, and provide the type of study best suited to the question or purpose.  **Submit** a 1-page document explaining your rationale for improving the questions by Sunday. Make sure to explain why the questions were not strong initially. | | 1.3 |  |
| **Research Design Exercise**  Researchers should begin by asking themselves the following questions:   * What type of question am I asking? * What types of data will I need to collect to answer these question? * What types of results will I report? How will I find these results?   **Describe** your research approach along with rationale for its suitability for addressing the research questions, citing appropriate methodological literature.  **Submit** a 250-word explanation of your research design. | | 2.2 |  |
| **Total** |  |  |  |

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| Week Three: Data Collection | |  |  |
| ***Learning Objectives*** | | ***Alignment*** | |
| * 1. Evaluate your data collection plan. | | CLO3 | |
| * 1. Assess your sample selection for your dissertation. | | CLO3 | |
| * 1. Determine your instrument for data collection. | | CLO3 | |
| ***Resources, Activities, and Preparation***  *Utilize these resources and complete these activities in preparation for your graded assignments.* | | ***Alignment*** | ***AIE*** |
| **Readings**   * Ch. 11 of *Surviving Your Dissertation*. * Ch. 5 of *Developing Quality Dissertations in the Social Sciences*. * Avoiding Poor Survey Questions * Examples of Bad Questions and Suggestions Of How To Fix Them! * [Are You Thinking About Being in a Research Study?](https://about.citiprogram.org/en/resources/). This article will help you visualize your study from the perspective of the participant. | |  |  |
| **Advisor Meeting**  **Meet** with your advisor to discuss your methodology. | |  |  |
| ***Graded Assignments***  *Complete these graded assessments by the end of the week unless specified otherwise.* | | ***Alignment*** | ***AIE*** |
| **Advisor Meeting Reflection**  **Meet** with your advisor to discuss your protocol. Respond to the following prompts about your meeting:   * What advice has your advisor offered related to your methodology, data collection, data analysis? * What questions did you pose to your advisor? * What questions remain about Ch. 3 or the IRB process?   **Submit** a 250-word reflection about your status by Sunday 11:59 PM. | | 3.1 – 3.3 |  |
| **Sample and Data Sources**  **Review** the sampling article by Dr. Trochim at the [Web Center for Social Science Research](http://www.socialresearchmethods.net/kb/sampling.php).  Preparing for your dissertation, **describe** the characteristics and size of the sample (quantitative, qualitative, and mixed methods) and/or data set (quantitative/mixed methods only, if applicable).  **Describe** participants in enough detail that the reader can visualize. Delineate important characteristics.  **Prepare** to justify your sample size for quantitative research using confidence level and confidence interval. Conduct a power analysis to determine sample size. A rule of thumb is +/- 5 % (margin of error) for the confidence interval of 95% confidence level (p= .05) is appropriate. To meet these standards for a population of 1,000 people, 278 participants are needed. For qualitative research, typically 3-4 focus groups or 25 interviews would be sufficient.  During the design of the study, the sample size calculation will indicate whether the study is feasible. During the review phase, it will reassure the reviewers that not only is the study feasible, but also that resources are not being wasted by recruiting more subjects than is necessary.  Who will be studied? Include inclusion criteria and exclusion criteria. Consider the location for your study. Explain your rationale for selecting your research site. If you are employed at this location, provide strong justification for not selecting another location. Examine the ethical considerations related to conducting research at your workplace, i.e. coercion, consent, bias, autonomy, and confidentiality.   * How will the participants be selected? * How will they be recruited?   **Describe** what methods will be used to recruit subjects. It is important to document that the study will be feasible and that there will be no ethical problems.  **Submit** a 1-page document outlining your sample and data sources by Sunday 11:59 PM. | | 3.1-3.2 |  |
| **Data Collection**  **Describe** the data collection methods and procedures, including how, when, where, and by whom data will be collected.   * + If a survey is used, the method of collecting the data, the rate of return, the description of procedures to follow-up, and the description of non-responders should be provided.   + Describe with enough detail that the reader could replicate the study, if desired.   + Where did the questionnaire come from? How was it developed?   + What does the survey consist of? Has it been pretested?   + Is your method a reliable and valid measure of the variables, i.e. satisfaction?   **Submit** a one-page description of the data collection procedures planned by Sunday 11:59 PM. | | 3.3 |  |
| **Reviewing a Bad Survey**  **Review** this Designing Better Survey Questions document. There are 10 questions that include common errors in survey question development.  **Find** the mistakes or errors in the survey questions. Improve the questions.  **Submit** your response using comments or track changesSunday 11:59 PM. | | 3.1-3.3 |  |
| **Instruments and Procedures**  **Select** one of the following options for your research methodology:   * Quantitative and Mixed Methods: Describe and justify the type of instrument(s), and provide the name/source if “off the shelf.”   + Explain the concepts measured, calculation of scores/values, pilot test if applicable, and instrument reliability and validity, with reference to appendices.   + If an unpublished instrument or new technique is being used, describe it in great detail. Conduct reliability and validity analyses. Evidence of reliability and validity should be clearly stated.   + List independent and dependent variables and their operational definition.   + You can use a diagram/figure of the design. * Qualitative Methods:     + Describe and justify any instruments used, such as interview, focus group, or observation protocols, with reference to appendices.   + Explain the advantages and disadvantages to your collection method.   **Submit** a draft of your survey if you chose the quantitative and mixed method or a draft of your interview questions if you chose thequalitative method by Sunday 11:59 PM. | | 3.3 |  |
| **Total** |  |  |  |

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| Week Four: Data Analysis | |  |  |
| ***Learning Objectives*** | | ***Alignment*** | |
| * 1. Evaluate data analysis plans for a dissertation. | | CLO3 | |
| * 1. Develop your data analysis plans for your dissertation. | | CLO3 | |
| * 1. Assess your biases, assumptions, and role as a researcher. | | CLO4 | |
| ***Resources, Activities, and Preparation***  *Utilize these resources and complete these activities in preparation for your graded assignments.* | | ***Alignment*** | ***AIE*** |
| **Readings**   * Ch. 6 & 7 of *Surviving Your Dissertation*. * [Data Analysis Toolkit](http://www.cal.org/twi/EvalToolkit/appendix/toolkit13_sec9.pdf) * [Basic Concepts in Research and Data Analysis](https://support.sas.com/publishing/pubcat/chaps/59814.pdf). * [PowerPoint on Data Analysis.](https://www.uio.no/studier/emner/matnat/ifi/nedlagte-emner/INF4260/h10/undervisningsmateriale/DataAnalysis.pdf) | |  |  |
| **Advisor Meeting**  **Meet** with your advisor to discuss your methodology. | |  |  |
| **Avoid Pitfalls of Data Analysis**  Given the various approaches to data analysis, here is a summary of the key pitfalls to avoid. First, Verhoef & Hilsden (2004) suggest that you must create a plan for data analysis that is clear. The following are a few of examples of effective approaches:   * The data will be analyzed with appropriate parametric and nonparametric tests using SPSS for Windows, Version 7.   + In other words, what it says to those reading your study is, “I do not have the foggiest idea about what I will be doing.” * The data will be analyzed using means, standard deviations, t-tests, chi-square tests, correlation coefficients, and analysis of variance.   + In other words, what it says to those reading your study is, “The data will be beaten with a bunch of statistical tests in hopes that it will talk.” * They add that listing statistical tests without explaining why you will conduct them does not demonstrate your preparation. If you plan to conduct a t-test, explain why you are doing that test. They advise the following:   + Devise an analysis plan, not a statistical shopping list.   + Descriptive analysis first   + Analytic tests second, which address specific research questions | |  |  |
| ***Graded Assignments***  *Complete these graded assessments by the end of the week unless specified otherwise.* | | ***Alignment*** | ***AIE*** |
| **Advisor Meeting Reflection**  **Meet** with your advisor to discuss your protocol. Respond to the following prompts about your meeting:   * What advice has your advisor offered related to your methodology, data collection, data analysis? * What questions did you pose to your advisor? * What questions remain about Ch. 3 or the IRB process?   **Submit** a 250-word reflection about your status by Sunday 11:59 PM. | | 4.1-4.3 |  |
| **Discussion: Improving Data Analysis Plans**    **Submit** a 250-word response explaining your assessment of the problems in the data analysis plans by Thursday 11:59 p.m. (EST). Cite articles, research, or texts to support your argument.   * Explain the problems with the following statements as data analysis plans:   + The data will be analyzed with appropriate parametric and nonparametric tests using SPSS for Windows, Version 7.   + The data will be analyzed using means, standard deviations, t-tests, chi-square tests, correlation coefficients and analysis of variance.   **Post** constructive criticism, clarification, additional questions, or your own relevant thoughts to 3 of your classmates' posts by 11:59 p.m. (EST) on Sunday. | | 4.1-4.3 | Discussion = **1 hour** |
| **Data Analysis**  **Choose** only one of the following options:  **Date Analysis for Qualitative:** For qualitative research, describe each technique you plan to use and provide a rationale for its use. Explain procedures for the following:   * Recording and storing data * Assessing the quality of your data * Thematic analysis   **Date Analysis for Quantitative:** For quantitative research, consider your assumptions regarding the statistical analysis, the rationale for each statistical technique chosen as well as the alpha levels for determining statistical significance. Explain procedures for the following:   * Recording and storing data * Assessing the quality of your data * Statistical analysis: Explain what each test is meant to show and what results you would have based on the test.   **Submit** a 1-page overview of your data analysis plan by Sunday 11:59 PM. | | 4.1-4.2 |  |
| **Reflection: The Role of the Researcher**  **Explain** your role as the researcher in planning and conducting the study; make explicit relevant researcher assumptions, beliefs, and biases (if applicable).  **Submit** a 250-word reflection on your assumptions, beliefs, and biases by Sunday 11:59 PM. | | 4.3 |  |
| **Total** |  |  |  |

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| Week Five: Ethical Treatment of Human Subjects | |  |  |
| ***Learning Objectives*** | | ***Alignment*** | |
| * 1. Explain the guiding principles for ethical conduct in clinical research. | | CLO5 | |
| * 1. Determine the implications of the ethical treatment of human subjects for dissertation research. | | CLO5 | |
| * 1. Complete the online CITI training for research involving human participants. | | CLO5 | |
| ***Resources, Activities, and Preparation***  *Utilize these resources and complete these activities in preparation for your graded assignments.* | | ***Alignment*** | ***AIE*** |
| **Readings**  **Read** the following resources:   * Ch. 13 of *Surviving Your Dissertation* * Belmont Report: National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Department of Health, Education and Welfare (DHEW). (1978[). The Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html). (DHEW pub. no. (OS) 78-0012). Washington, DC: United States Government Printing Office. | | ULO5 |  |
| **Advisor Meeting**  **Meet** with your advisor to discuss your methodology. | |  |  |
| ***Graded Assignments***  *Complete these graded assessments by the end of the week unless specified otherwise.* | | ***Alignment*** | ***AIE*** |
| **Discussion: The Belmont Report’s Guiding Principles**    **Respond** to the following prompts in the [Belmont Report’s Guiding Principles](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html) by Thursday 11:59 p.m. (EST). Provide specific examples to support your answers:   * Consider respect for persons, beneficence, and justice. * Explain how the Belmont Report’s three guiding principles for the ethical conduct of clinical research impact your research design, your research question, and the informed consent of your participants. * Share specific examples of how these concepts have guided your research design.     **Post** constructive criticism, clarification, additional questions, or your own relevant thoughts to 3 of your classmates' posts by 11:59 p.m. (EST) on Sunday. | | 5.1, ULO5 | Discussion = **1 hour** |
| **Discussion: Ethical Treatment**    **Respond** to the following prompts by Thursday 11:59 p.m. (EST). Provide specific examples to support your answers:   * Evaluate your understanding of the treatment of human participants in terms of privacy, confidentiality, consent, and permission. Consider the ethical principles of autonomy, * Consider protecting data, storing data, recording data, and transcribing data. * What do you need to do to protect your participants from data breaches or having their data revealed? * What do you need to do inform your participants about the risks and benefits of the research? * What are the risks? How will you protect the participants?   **Post** constructive criticism, clarification, additional questions, or your own relevant thoughts to 3 of your classmates' posts by 11:59 p.m. (EST) on Sunday. | | 5.2, ULO5 |  |
| **CITI Training and Certification**  **Complete** the Research: Protecting Human Research Participants course.  *Note:* This course is free to you because the university is covering the cost. It may take about 20 hours to complete. It does not have to be completed in one session.  **Save** your certificate and certificate number upon completion. This number must be included in your research proposal for the Institutional Review Board (IRB).  **Submit** you CITI Certification by Sunday 11:59 PM | | 5.3, ULO5 |  |
| **Total** |  |  |  |

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| Week Six: IRB Draft |  |  |
| ***Learning Objectives*** | ***Alignment*** | |
| * 1. Analyze the IRB process. | CLO4 | |
| * 1. Develop your IRB protocol proposal. | CLO4 | |
| ***Resources, Activities, and Preparation***  *Utilize these resources and complete these activities in preparation for your graded assignments.* | ***Alignment*** | ***AIE*** |
| **Readings and Videos**  **Readings**   * The Student IRB Handbook. You will access the handbook through the IRB Community in the GMercyU portal. * The IRB Training Presentation to help you navigate the forms. * IRB002 Form Rubric for Review * Checklist for IRB Submission   **Videos**   * [Adobe Connect Training Session](http://gwynedd-mercycollege.adobeconnect.com/p6cozhlrfcd/?OWASP_CSRFTOKEN=b46c69bdc5bba0a070da1dd1614dc5c902c217f9f07153c257b7429162aa6f12) about the [IRB at GMercyU](http://gwynedd-mercycollege.adobeconnect.com/p6cozhlrfcd/?OWASP_CSRFTOKEN=b46c69bdc5bba0a070da1dd1614dc5c902c217f9f07153c257b7429162aa6f12). |  |  |
| **Consent Procedures: Creating Informed Consent**  **What information is included in a consent form?**   * A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental * A description of any reasonably foreseeable risks or discomforts to the subject * A description of any benefits to the subject or to others that may be reasonably expected from the research * A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject * A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be maintained * For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained * An explanation of whom to contact for answers to pertinent questions about the research and research subject’s rights, and whom to contact in the event of a research-related injury to the subject, if relevant. Typically, questions concerning a research project should be referred to the principal investigator (PI) for that project, whereas questions concerning the rights of human subjects should be referred to the IRB. * A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue * Participation at any time without penalty or loss of benefits to which the subject is otherwise entitled   Other requirements may apply. |  |  |
| **Advisor Meeting**  **Meet** with your advisor to discuss your methodology. |  |  |

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| ***Graded Assignments***  *Complete these graded assessments by the end of the week unless specified otherwise.* | | ***Alignment*** | ***AIE*** |
| **Form IRB001**  **Download** the [IRB Student & Investigator Handbook](https://na01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmy.gmercyu.edu%2Fgroup%2Finstitutional-research-board%2Fhome%3Fp_p_id%3D20%26p_p_lifecycle%3D0%26p_p_state%3Dmaximized%26p_p_mode%3Dview%26p_p_col_id%3Dcolumn-2%26p_p_col_count%3D1%26_20_struts_action%3D%252Fdocument_library%252Fview%26_20_folderId%3D1954268%26_20_tabs1%3DFolders&data=02%7C01%7Camiller%40synergiseducation.com%7C510a89de864c4d69bf6408d67763e4b4%7C7a9bcbb102ab4062aafc53c0ba30b9ac%7C0%7C0%7C636827668278685841&sdata=E86I2pe0fayIV9elv0BYMj7HBAleN%2FvqvCLcM8JeFAU%3D&reserved=0) from Gwynedd Mercy University’s Student portal. This handbook includes various forms that will be used for IRB Assignments in this course.  **Complete** Form IRB001, located in the IRB Student & Investigator Handbook. This form will help you understand all the components necessary for a proposal to be approved.   * The course instructor and your advisor should offer feedback to improve your proposal. Follow the directions in the Investigator’s Handbook, review the webinar for IRB, and submit the completed document. Be sure to address privacy, confidentiality, consent, research methods, data analysis, and permission.   Key Considerations for your Research:   * For the dates of your research, select the week after your proposal will be reviewed as the beginning date, and provide yourself with about 6 months to complete the research. You can finish more quickly, but you would need to reapply with revised dates if you need more time. * If you have a relationship with the research location, disclose it in your proposal. If you have the options to do research at a location where you do not have a personal or professional relationship, you remove the potential for bias or coercion. * If the location (institution or organization) is identified, or if they are giving access to information that you would not otherwise have, you need permission from that location. * Consider all information from the perspective that you do not work there. If you access information because of your job, you will need permission from your employer—someone who is authorized to give permission on behalf of that organization. You must explain every single detail or step. Be extremely critical in your writing. Include risks to participants and also risks to investigators. You must provide protection for each risk. Include an explanation in the risk–benefit ratio.   **Submit** your completed Form IRB001 by Sunday 11:59 PM. | | 6.1-6.2 |  |
| **Form IRB004**  **What kinds of IRB review are there?** There are three levels of IRB Review (full review, expedited review, and screening for exemption), determined by the nature of the protocol, level of potential risk to human subjects, and the subject population. The determination of level of review applicable to a particular study is made by the IRB. Regardless of the kind of review, all applications use the same submission form.   * **Screening for exemption:**Research with very minimal risk to human subjects as determined by regulatory guidelines may be exempted from further review at the discretion of the IRB. * **Expedited IRB review:**Only research involving no more than minimal risk to subjects may be considered for expedited review. Federal guidelines provide categories for expedited review. Examples of categories include review of records collected for non-research purposes (such as chart reviews) and survey research. * **Full review:**Any study involving greater than minimal risk requires a review by the convened IRB. This includes studies with vulnerable populations and sensitive questions, as well as studies with the possibility of physical or emotional risk.   **Complete** Form IRB004, located in the IRB Student & Investigator Handbook, based on the level of your review.  **Follow** the directions in the Investigator’s Handbook, and **submit** the completed form in Bb.  *Note:* Be advised that if your research involves a vulnerable population (minors, pregnant women, prisoners, etc.), you will need a full review, which only occurs once a semester, usually at the end.  **Submit** your Research Type IRB 004 form by Sunday 11:59 PM | | 6.1-6.2 |  |
| **Improving the IRB Protocol Activity**  In most cases, the researcher does not explain clearly or in great enough detail what is necessary to protect data and participants.  **Access**the Research Proposal Review Form﻿﻿, located in Blackboard  **Review** the sample answers in the Research Proposal Activity document, also located in Blackboard.  **Evaluate** the answers and focus on risks, benefits, the ratio, protections, and consent.  **Provide** clear and extremely detailed information. Do not assume the committee member can interpret or estimate your intentions.  **Make comments** in the Research Proposal Activity document on ways you would add to and revise the document. Make sure to use track changes.  **Write** a 250-word response, in a separate document, to how the IRB process could be improved for students. You may write your response in the Research Proposal Activity document,  **Submit** your two documents, the Research Proposal Activity and the 250-word response, by Sunday 11:59 PM. | | 6.1-6.2 |  |
| **Advisor Meeting Reflection**  **Meet** with your advisor to discuss your protocol. Respond to the following prompts about your meeting:   * What advice has your advisor offered related to your methodology, data collection, data analysis? * What questions did you pose to your advisor? * What questions remain about Ch. 3 or the IRB process?   **Submit** a 250-word reflection about your status by Sunday 11:59 PM. | | 6.1-6.2 |  |
| **Total** |  |  |  |

# Faculty Notes

**IRB Handbook:** Check that the IRB Handbook is the most recent version

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| Week Seven: Refining the IRB and Dissertation Proposal | |  |  |
| ***Learning Objectives*** | | ***Alignment*** | |
| * 1. Assess your research design, methodology, data collection, and data analysis. | | CLO4 | |
| * 1. Complete the IRB proposal based on feedback from course instructor and advisor. | | CLO4 | |
| ***Resources, Activities, and Preparation***  *Utilize these resources and complete these activities in preparation for your graded assignments.* | | ***Alignment*** | ***AIE*** |
| **Advisor Meeting**  **Meet** with your advisor to discuss your methodology. | |  |  |
| ***Graded Assignments***  *Complete these graded assessments by the end of the week unless specified otherwise.* | | ***Alignment*** | ***AIE*** |
| **Discussion: Dissertation Obstacles**  This exercise is to help you and your classmates overcome a current obstacle in the dissertation process. Providing feedback that offers constructive insight into an area that needs to be further developed will be extremely helpful.    **Submit** a 1-page document for critical review by classmates by Thursday 11:59 p.m. (EST). Provide specific examples to support your answers to the following questions:     * What gaps exist in first three chapters? * Where do you need a critical reviewer? * Where are you struggling to add the academic rigor necessary? * Have you built a strong theoretical argument in your literature review? * Are your research questions academically appropriate and well written? * Are there flaws in your research design? * Have you tested your reliability/validity of your instrument? * Reflect on your challenges and choose one area to improve.   **Post** constructive criticism, clarification, additional questions, or your own relevant thoughts to 2 of your classmates' posts by 11:59 p.m. (EST) on Sunday. | | 7.1 | Discussion = **1 hour** |
| **Reflection**  **Submit** a 250-word journal reflection about your status and your goals to complete the dissertation by Sunday 11:59 PM.   * What have you accomplished in this course? * What work, research, or reading is remaining? * Assess your timeline. Does your advisor think your timeline is reasonable? Why or why not? | | 7.1 |  |
| **The IRB Proposal Submission**  **Assemble** all components of the IRB proposal, incorporating final feedback from your dissertation advisor.  **Submit** your proposal by Sunday 11:59 PM in Blackboard. | | 7.2 |  |
| **Total** |  |  |  |

# Breakdown of Academic Instructional Equivalencies

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| --- | --- |
|  | **AIE Hours** |
| **Week 1** |  |
| Required |  |
| Supplemental |  |
| **Week 2** |  |
| Required |  |
| Supplemental |  |
| **Week 3** |  |
| Required |  |
| Supplemental |  |
| **Week 4** |  |
| Required |  |
| Supplemental |  |
| **Week 5** |  |
| Required |  |
| Supplemental |  |
| **Week 6** |  |
| Required |  |
| Supplemental |  |
| **Week 7** |  |
| Required |  |
| Supplemental |  |
|  |  |
| **Total Required Hours** |  |
| **Total Supplemental Hours** |  |
| **Total Hours** |  |